REMARKS

In the Office Action dated June 9, 2005, claims 1-16 were examined with the result that all claims were rejected. The Examiner made the rejection final. In response, Applicant has filed a Request for Continuing Examination (RCE) and the following comments. In view of these comments, reconsideration of this application is requested.

In the Office Action, claims 1-16 were rejected under 35 USC §112, first paragraph, as failing to comply with the enablement requirement. The Examiner's position is that one skilled in the art could not practice the invention without undue experimentation. More specifically, in the "Response to Remarks" section of the Office Action, the Examiner set forth three issues relating to this rejection. These issues are:

1. The Examiner indicated that the data are confusing as an increase in life expectancy in rats is different from an increase in life expectancy in human beings. In addition, the Examiner questioned why ovariectomized female rats were utilized to obtain the data instead of normal female rats. Finally, the Examiner requested an explanation as to how the data supports a claim to increasing the life expectancy of human beings.

2. The second issue revolved around independent claim 12 which had previously been amended to call for inhibiting tumorogenesis in the treatment of breast cancer. The Examiner requested Applicant explain how the text provides support for the treatment of breast cancer.

3. The Examiner requested clarification regarding the arguments based on U.S. 5,843,928 presented in the previous response dated February 3, 2005.

With regard to the first issue set forth above, it has long been recognized that a rat model is indicative of what might happen in humans, and has long been established as an acceptable model for correlating biological data to humans. Thus, data in rats has been for many years correlated to humans, and Applicant believes that rat data evidencing increase in life expectancy in rats correlates to increasing life expectancy in human beings. If the Examiner desires, Applicant can cite numerous published articles that support its position. However, the fact that rat models correlate to human models has long been accepted by those skilled in the art.

Ovariectomized female rats were utilized in the experiments because ovariectomized female rats will generally develop mammary tumors and the experiment was initially designed to determine whether 2-methylene-19-nor-(20S)-1,25-dihydroxyvitamin D_3 (2MD) would be effective to prevent tumorogenesis in the mammaries of these older ovariectomized female rats. Surprisingly, however, it was also noticed that the survival rate of these female rats was significantly increased if they were administered 2MD. The experiment set forth on pages 6 and 7 of the specification was carried on for 7-1/2 months with one half of the animals receiving a vehicle and the other half of the animals receiving 2MD. All other conditions were the same, i.e. all animals were substantially identical, they received substantially the same diet, and they were housed in a substantially identical environment. During the course of this 7-1/2 month experiment, all the animals that received 2MD survived and were in good health. In contrast, at least three of the control animals failed to survive due to the development of mammary tumors. A fourth died of unknown causes. These data clearly show that all of the treated animals survived, thus increasing their life expectancy, whereas a significant number of the untreated animals failed to survive due to the development of cancerous breast tumors. It is to be particularly noted that the data in Table 1 is in fact statistically significant. Applicant believes the data illustrate increased life expectancy, and thus the data support claims 1-5 as filed. As noted, 16.7% of the rats (4 of 24) died in the untreated or control group whereas 0% of the rats died in the group treated with 2MD.

In addition, since the rats were all retired female breeder rats 12 months of age or older, and were all ovariectomized, Applicant believes the data further illustrate the ability of 2MD to increase the life expectancy of females lacking estrogen. Clearly, all of the rats were females and all lacked estrogen. All of the rats treated with 2MD survived, and thus had increased life expectancy over those in the untreated group, a significant number of which died. Thus, Applicant believes these data support claims 6-11.

With regard to the second issue noted above, support for claim 12 which calls for a method of inhibiting tumorogenesis in the treatment of breast cancer can be found at page 7, lines 6-13 of the description as filed. Applicant states therein that at least three of the untreated rats failed to survive due to the development of mammary tumors. In contrast, none of the rats treated with 2MD developed mammary tumors. Thus, the only conclusion that can be made is that 2MD inhibits tumorogenesis in the mammaries of the rats. In addition, original claim 19 as filed defined the cancer as being breast cancer. Thus, claim 12 was amended to be specific to the inhibition of tumorogenesis in the treatment of breast cancer. Applicant believes the data and description on page 7 of the application as filed, as well as original claims 12 and 19 as filed, support a claim to a method of inhibiting tumorogenesis in the treatment of breast cancer by administering 2MD as currently called for in independent claim 12. These data illustrate that untreated animals developed breast tumors whereas animals treated with 2MD did not. Therefore, Applicant believes these data support a claim to the inhibition of tumorogenesis and the treatment of breast cancer.

Finally, the third issue referred to by the Examiner relates to the arguments surrounding U.S. 5,843,928. The Examiner will remember, however, that the previous Office Action contained an obviousness type double patenting rejection over the claims of copending Application 10/780,103. Rather than file a Terminal Disclaimer, Applicant attempted to argue the unobviousness of the biological activities between 2MD and the 26,27-dihomo compounds covered by the '103 application. The reference to U.S. 5,843,928 was only made by Applicant because the '928 patent contains the published

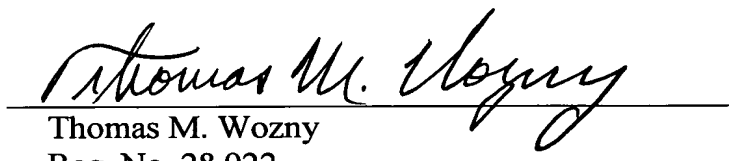
biological calcemic activity data for 2MD. Thus, Applicant was merely referring the Examiner to the '928 patent as a disclosure of the calcemic activities of 2MD. Applicant was not attempting to utilize the data in the '928 patent to somehow support the present claims to increasing the life expectancy of human beings. The reference to the '928 patent was merely made in an attempt to point the Examiner to a published document containing the calcemic data for 2MD so that these data could be compared to the data for the 26,27-dihomo compounds set forth in the '103 application in an attempt by Applicant to overcome the obviousness type double patenting rejection set forth in the previous Office Action.

As the Examiner has withdrawn the obviousness type double patenting rejection in the present Office Action, Applicant believes these arguments are now moot.

An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP

By 
Thomas M. Wozny
Reg. No. 28,922

Andrus, Sceales, Starke & Sawall, LLP
100 East Wisconsin Avenue, Suite 1100
Milwaukee, Wisconsin 53202
Telephone: (414) 271-7590
Facsimile: (414) 271-5770